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510(K) NOTIFICATION

Sigma Diagnostics
545 South Ewing Avenue
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CX³ CO₂ Alkaline Buffer
Procedure Number C7683
August 31, 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

Carbon dioxide (CO₂) in serum or plasma exists primarily as dissolved CO₂ and bicarbonate anion (HCO₃⁻).¹ The CO₂ content is decreased in metabolic acidosis and respiratory alkalosis, whereas the level is increased in metabolic alkalosis and respiratory acidosis.² In pathologic conditions such as in diabetes mellitus, glomerulonephritis, pyloric obstruction, or diarrhea, acidosis or alkalosis can be anticipated.³ Therefore, determination of plasma CO₂ content as part of an electrolyte profile helps establish whether, and to what degree, the anticipated change has occurred in the above patients.

The safety and effectiveness of Sigma Diagnostics CO₂ Alkaline Buffer, Procedure Number C7683, are demonstrated by its substantial equivalency to Beckman CO₂ Alkaline Buffer Kit, Part No. 443320. Both CO₂ alkaline buffers are used to measure carbon dioxide concentrations in serum or plasma on the SYNCHRON CX³ System, and the reaction principles for both are identical. In comparison studies, a correlation coefficient of 0.992 and a regression equation of $y = 0.95x + 1.54$ was obtained with serum samples. With-in run precision and total precision on serum samples demonstrated %CV's of less than 6.5 %. The Sigma Diagnostics CO₂ Alkaline Buffer has been determined to be linear from 5.0 to 40.0 mmol/L on the SYNCHRON CX³ System.

REFERENCES

1. Clinical Chemistry, LA Kaplan, AJ Pesce, Editors, CV Mosby Company, St. Louis (MO) 1989
2. Hydrogen Ion Concentration in Body Fluids. IN Contarow and Trumper Clinical Biochemistry, 7 th ed., AL Latner, Editor, Saunders, Philadelphia, 1975, p 399
3. Tietz, NW, Prudent EL, Siggaard-Anderson O: Electrolytes, Blood Gases, and Acid-Base Balance. IN Textbook of Clinical Chemistry, NW Tietz, Editor, Saunders, Philadelphia, 1986, p 1188